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May 19, 2004

Michael Leavitt, Administrator  
U.S. Environmental Protection Agency  
Ariel Rios Bldg. (1101A)  
1200 Pennsylvania Ave., NW  
Washington, DC 20460

Re: Comments on the API's Test Plan for the Reclaimed Substances Category

Dear Administrator Leavitt:

The following comments on the American Petroleum Institute (API) High Production Volume (HPV) Challenge test plan for Reclaimed Substances are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

This test plan represents yet another incomprehensible proposal by the API to conduct new and avoidable animal testing rather than analyze existing data. There is no evidence that the API made any effort to obtain the study records from the existing studies, which include a 90-day repeat dose study that included developmental endpoints, a one-generation reproduction study on rabbits, *in vitro* genetic toxicity tests, a recent developmental toxicity study, and a recent two-year carcinogenicity bioassay. Instead, the test plan proposes a virtually full slate of animal testing, including a combined repeat dose/reproduction/developmental toxicity test (OECD 422), an *in vivo* genetic toxicity test (OECD 474), and an acute fish toxicity test (OECD 203) that will result in the suffering and deaths of approximately 800 animals.

The API's proposal to conduct another fish toxicity test on naphthenic acids does not make sense either. Four tests of naphthenic acids have been carried out previously on adult fish, in addition to one on fish embryos (robust summaries, pp. 21-26), and no explanation is given as to why an additional test is required. Furthermore, the test plan states that the partition coefficients for modeled naphthenic acid structures are higher than 5 (test plan, p. 15). The API needs to clarify this as the EPA has stated that acute fish toxicity tests should not be carried out on compounds with log  $K_{ow}$  above 4.2 (*Federal Register*, Dec. 26, 2000, vol. 65, no. 248, p. 81695). While the API states that the modeled partition coefficients are not certain, it does not make any proposal to ascertain them experimentally.

Further, the reclaimed substances test plan contains almost no chemical characterization of the various streams, with none of the specific compounds having any concentration data or specific chemical structures analyzed in the test plan. Before the API undertakes any testing, it is critical to characterize the composition of these streams and to use existing data on substances with known composition to better understand these chemical's toxicity. Naphthenic acid itself is not a distinct compound, but rather a mixture of many non-aromatic, cyclic carboxylic acids. Several other categories have similar substances that may shed light on the toxicity of the compounds in



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this category. The gas oils, petroleum oxidates, dicarboxylic acid, alkylphenols, and many other categories could provide some insight into the toxicity of these compounds and allow a better understanding of the relevant toxicological issues.

The API has made some good decisions in its test plan by not proposing to test any products containing caustics or intermediate process materials with minimal chance of human or ecological contact (these streams generally do not leave the refinery or are sold as products). However, the API is clearly violating basic animal welfare provisions as set forth by the EPA, including the guidance to use *in vitro* genetic toxicity tests unless physical properties preclude this approach as well as the requirement to maximize the use of existing data. The API's failure to exert itself by offering a more complete evaluation of the existing data will lead directly to the suffering and death of hundreds of animals.

I can be reached at 757-622-7382, ext. 8001, or via e-mail at [JessicaS@peta.org](mailto:JessicaS@peta.org).

Sincerely,

Jessica Sandler  
Federal Agency Liaison